

REMARKS

Upon entry of the present amendments, claims 1-10, 12-17, 21, 23-29, and 44-45 will be pending in the application. Claims 18-20 and 30-43 have been cancelled herein without prejudice or disclaimer, as being directed to a nonelected invention. Claims 11 and 22 have been cancelled herein, without prejudice or disclaimer. Claims 14, 17, 23-27, and 29 have been allowed. Claims 1, 4, 7-10, 12, 21, and 28 have been amended. Support for the amendments to these claims can be found throughout the as-filed specification. New claims 44 and 45 have been added herein. Support for these claims can be found throughout the as-filed specification.

Thus, no new matter has been added.

Election/Restriction

The Examiner has indicated the claims 18-20 and 30-43 have been withdrawn from further consideration as being drawn to a nonelected invention. (See Office Action at page 2). Claims 18-20 and 30-43 have been cancelled herein, without prejudice or disclaimer, as being drawn to a nonelected invention.

Allowable Subject Matter

Applicant notes with appreciation that the Examiner has indicated that claims 14, 17, 23-27, and 29 are allowed.

Claim Rejections -- 35 U.S.C. § 112

Claims 7 and 13 have been rejected under 35 U.S.C. § 112, first paragraph as based on a disclosure that is not enabled. According to the Examiner, “the appropriate ATCC numbers and required Deposit information critical or essential to the practice of the invention, as it relates to monoclonal antibodies [*sic.*] SC20 (8G1.7), but not included in the claim(s) is not enabled by the disclosure.” (Office Action at page 2). The Examiner further notes that the specification lacks sufficient deposit information for this monoclonal antibody. (See Office Action at page 3).

As an initial matter, Applicants note that claim 7 has been amended herein to remove the reference to monoclonal antibody SC20. Thus, Applicants contend that this rejection is moot as it applies to claim 7, as amended herein, and should be withdrawn.

Moreover, as suggested by the Examiner, Applicants have herein amended page 21 of the instant specification to recite the date of deposit to the ATCC for monoclonal antibody SC20 (8G1.7) (*i.e.*, December 20, 1999) and to include a statement that, in accordance with the provisions of the Budapest Treaty, all restrictions on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent.

Applicants have also amended page 21 of the specification to remove the reference to ATCC accession number PTA-994.

Thus, for these reasons, Applicants submit that this rejection has been overcome and should be withdrawn.

The Examiner has also rejected claims 1-10, 12, 15-16, 21-22, and 28 under 35 U.S.C. § 112, first paragraph for lack of enablement. According to the Examiner, “the specification, while being enabling for a method of producing a population of enriched human CNS stem cells using identifiable/deposited antibodies, does not reasonably provide enablement for methods of isolating enriched populations of human CNS stem cell using unknown or uncharacterized ‘reagent[s] that specifically binds to the CD49f antigen’, and/or that no longer bind to a CD24 antigen.” (Office Action at page 4). Applicants traverse.

Claim 22 has been cancelled herein. Thus, this rejection, as it applies to this claim, is moot and should be withdrawn. In an effort to facilitate the prosecution of this case, Applicants have herein amended claims 10, 21, and 28 to specify that the reagent that binds to CD49f is at least one antibody selected from the group consisting of monoclonal antibody GoH3 and monoclonal antibody 4F10 (*see* claim 21) or that CD49f⁺ cells are selected using an anti-CD49f antibody selected from the group consisting of monoclonal antibody GoH3 and monoclonal antibody 4F10 (*see* claims 10 and 28). Therefore, Applicants submit that this rejection, as it applies to claims 10, 21, and 28 (in part), has been overcome and should be withdrawn.

Contrary to the Examiner’s position, Applicants submit that the instant specification provides ample guidance to enable those skilled in the art to make and use the invention recited

in claims 1-9, 12, 15-16, and 28, without undue experimentation. Applicants note that CD49f, CD133 and CD24 are all well-known antigens, and the generation of monoclonal antibodies that bind to well-known, characterized antigens is within the routine skill of the ordinarily skilled artisan. In addition, numerous antibodies recognizing these well-known antigens are known in the art and are commercially available. (See specification at page 16, line 30 through page 17, line 7 (CD49f); page 14, line 30 through page 15, line 4 (CD133); and page 15, line 22 through page 16, line 9 (CD24)). Thus, to the extent that they reference monoclonal antibodies that recognize the CD24 antigen, monoclonal antibodies that bind to CD49f; monoclonal antibodies that bind to CD133; cells that are CD24^{-lo}; cells that are CD24⁺; and/or cells that are CD49f⁺. Applicants contend that those skilled in the relevant art would be able to make and use the invention recited in claims 1-9, 12, 15, 16 and 28, without undue experimentation.

Therefore, for all of the reasons articulated above, Applicant contends that, contrary to the Examiner's position, claims 1-10, 12, 15-16, 21, and 28, as amended herein, are fully enabled by the specification. As such, this rejection should be withdrawn.

Claim 4 has been rejected under 35 U.S.C. § 112, second paragraph as being indefinite for including a broad recitation ("flow cytometry") followed by a narrower recitation ("fluorescence activated cell sorting"). (See Office Action at page 5).

In response, Applicants have herein amended claim 4 to specify that "the selecting is by flow cytometry, fluorescence activated cell sorting, or high gradient magnetic selection." Thus, Applicants submit that claim 4, as amended herein, is not indefinite. Therefore, this rejection should be withdrawn.

The Examiner has also rejected claims 7 and 8 under 35 U.S.C. § 112, second paragraph as being indefinite. According to the Examiner, "[i]n that SC20 appears to be a monoclonal antibody designation, versus a well-known antigen designation, claim 7 is indefinite." (Office Action at page 6). Applicants traverse.

In response, Applicants have herein amended claim 7(d) to recite "removing those cells that are CD24⁺". Thus, this amended claim refers to a well-known antigen (*i.e.*, CD24) as

opposed to a monoclonal antibody (*i.e.*, SC20). Thus, this rejection, as it applies to claim 7, should be withdrawn.

In addition, the Examiner has also indicated that the recitation of the limitation “**the anti-CD133 monoclonal antibody**” in claim 8 renders it unclear because the specification indicates that monoclonal antibodies AC133 and SC111 bind to CD133. (Office Action at page 6 (emphasis in original)). As such, the Examiner concludes that “it is unclear what **the anti-CD133 monoclonal antibody** actually constitutes.” (Office Action at page 6 (emphasis in original)). Applicants traverse.

Claim 8 has been amended herein to specify that the population of cells obtained according to the method of claim 1 are also contacted with a monoclonal antibody that binds to CD133 and that those cells that bind to the monoclonal antibody that binds to CD133 are then selected. Applicants submit that those skilled in the relevant art would be able to understand what is meant by the limitation “monoclonal antibody that binds to CD133”. In fact, two examples of such monoclonal antibodies are provided in the instant specification, namely monoclonal antibody AC133 and monoclonal antibody SC111. (*See, e.g.*, page 15, lines 3-4). Thus, Applicants contend that claim 8, as amended herein, is clear and not indefinite. As such, this rejection should be withdrawn.

Claims 1-13 have also been rejected under 35 U.S.C. § 112, second paragraph as being indefinite. Specifically, the Examiner notes that claims 1 and 10 are incomplete for omitting essential steps. According to the Examiner, “[t]he omitted steps are: selection of ‘progenitors, or combination thereof’, as recited in the preamble.” (Office Action at page 6). Applicants traverse.

Claims 1 and 10 have been amended herein to remove the phrase “progenitors, or a combination thereof”. Thus, Applicants submit that claims 1-13, as amended herein, are not missing any essential steps. Therefore, this rejection has been overcome and should be withdrawn.

Claims 21-22 also have been rejected under 35 U.S.C. § 112, second paragraph as being indefinite. According to the Examiner, “[i]t is ambiguous and contradictory what constitutes a

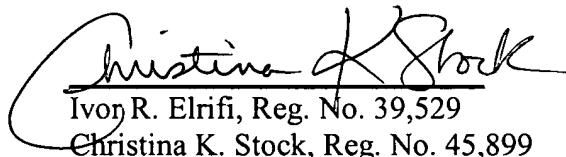
‘reagent’ . . .’ (Office Action at page 7). Moreover, the Examiner also notes that “it is ambiguous when a ‘reagent *specifically* binds . . .’, versus no longer ‘*specifically* binds’, in that the term ‘specifically binds’ is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention; thereby, rendering this claim further indefinite.” (Office Action at page 7 (emphasis in original)). Applicants traverse.

Claim 22 has been cancelled herein. Thus, this rejection, as it applies to this claim, is moot and should be withdrawn. Moreover, claim 21 has been amended herein to specify that the reagent is at least one monoclonal antibody selected from the group consisting of monoclonal antibody GoH3 and monoclonal antibody 4F10. Claim 21 has also been amended to delete the limitation “specifically”. Accordingly, Applicants submit that this rejection of claim 21 has been overcome and should be withdrawn.

CONCLUSION

Applicants submit that this paper is fully responsive and that the application is in condition for allowance. Such action is respectfully requested. Should any questions or issues arise concerning the application, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

Respectfully submitted,



Dated: August 14, 2006

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